Artificial Intelligence: Understanding the Regulatory Environment, Payment and CPT Coding

July 2, 2024

1:00 – 2:00 PM ET

Q&A will take place at the end of the program

You can submit written questions using the **“Questions” tab** (not chat) at any time during the webinar.

Webinar is being recorded

The recording and slides will be available on the NAACOS website within 48 hours.

Speakers

Shannon Curtis is the Assistant Director of Federal Affairs at the American Medical Association. In this role she manages AMA's advocacy with numerous federal departments and agencies and plays a key role in development of AMA policy on a wide range of healthcare issues. Her portfolio includes drug and device regulation and payment; public health, infectious disease and life science issues; reproductive health; and a number of issues that impact patient access and costs, such as drug pricing, healthcare price transparency, and competition. She has a significant focus on the regulation of digital health and AI-enabled technologies. Prior to joining the AMA, Shannon was part of the advocacy staff at the American Academy of Ophthalmology and the Association of American Medical Colleges, and was a legal fellow at the U.S House of Representatives. Shannon received her B.S. from the University of Colorado at Boulder and her J.D. from Southern Methodist University.

Samantha Ashley is the Director of CPT Editorial and Regulatory Affairs in the American Medical Association's Health Solutions business unit. Samantha's role is multifaceted, encompassing setting strategic direction for the CPT Editorial Panel process, as well as overseeing the communication of healthcare policies, through identification and resolution of national payment and reporting problems. She is also the Secretary of the CPT Editorial Panel, ensuring that the process remains open and transparent. In addition to her role with the CPT Editorial Panel, Samantha contributes her strategic insights to the AMA-convened Digital Medicine Payment Advisory Group (DMPAG) Notably, Samantha was lead staff for the DMPAG's AI Workgroup, when they developed seminal work in describing AI medical services within the CPT code set.

Cybil Roehrenbeck is a Partner in the Government Relations practice of global law firm Hogan Lovells LLP and leads the firm's healthcare lobbying practice. Cybil has over 20 years of experience in healthcare and government relations and frequently leads advocacy campaigns for national trade associations, innovator companies, healthcare providers, and multi-stakeholder coalitions.

Cybil previously worked as a lobbyist and attorney for the American Medical Association (AMA), where she advocated before Congress and officials from the U.S. Department of Health & Human Services on issues related to digital health, value-based care, health reform, and program integrity. She also spent five years on Capitol Hill as a legislative counsel to Representative Walter B. Jones (R-NC) and Committee liaison, where she was lead staff for the House Home Health Caucus.

Cybil began her career as staff for the House Republican Conference under Chair U.S. Representative J.C. Watts, Jr. (R-OK). Cybil also serves as Executive Director of the AI Healthcare Coalition, which advocates on behalf of healthcare AI innovators. She serves on the American Bar Association (ABA) Standing Committee on Governmental Affairs, and as Chair of the ABA Health Law and Policy Committee. Cybil is an Adjunct Associate Professor at American University Washington College of Law, where she teaches health law and policy, and a frequent speaker at national health law and advocacy conferences.

AMA AI Policies, Principles, & Perspectives

Shannon Curtis, JD
Assistant Director, Federal Affairs

March 2024

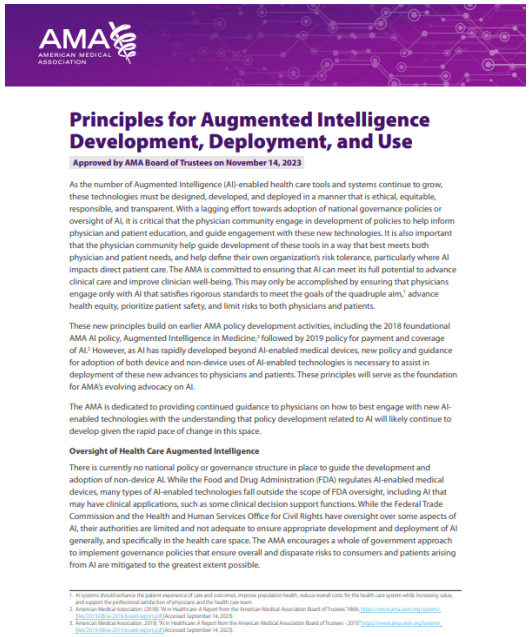
Federal Regulation of AI

FDA	FTC
• Authority to regulate medical devices only • Over 700 AI-enabled devices approved across specialties • Regular medical device review process – no new regulatory structure for SaMD or AI at this time • Some new guidance for AI/ML: Good Machine Learning Practices (GMLP); Predetermined Change Control Plans (PCCP) • New guiding principles for transparency – not mandatory	• Charged with consumer protection and regulation of competition • Limited action on AI to date, but has provided guidance • Deception and misleading AI claims – ex. claiming AI is better than humans without evidence; not disclosing an individual is interacting with AI • Unfair business practices – bias/discrimination; lack of transparency; data integrity

AMA Concerns with Current Oversight Structures

- Many AI-enabled technologies with potential for significant impact on clinical decision making may fall outside FDA regulatory purview
    - Clinical Decision Support (CDS) tools like ChatGPT and others are NOT regulated by FDA
- FDA has no transparency requirements/updated labeling for AI-enabled devices
    - Many agencies declining to institute transparency requirements for healthcare AI, making technology selection and appropriate use difficult – ONC is exception
- No consensus standards/governance policies for AI design, development, deployment – how do we know what “good” AI looks like?
    - No widely accepted AI validation services to help ensure performance/safety
- Physicians could be liable for the poor performance of AI – shared decision making raises novel liability questions

Principles for AI Development, Deployment and Use (2023)



AMA
AMERICAN MEDICAL ASSOCIATION

Principles for Augmented Intelligence Development, Deployment, and Use

Approved by AMA Board of Trustees on November 14, 2023

As the number of Augmented Intelligence (AI)-enabled health care tools and systems continue to grow, these technologies must be designed, developed, and deployed in a manner that is ethical, equitable, responsible, and transparent. With a lagging effort towards adoption of national governance policies or oversight of AI, it is critical that the physician community engage in development of policies to help inform physician and patient education, and guide engagement with these new technologies. It is also important that the physician community help guide development of these tools in a way that best meets both physician and patient needs, and help define their own organization's risk tolerance, particularly where AI impacts direct patient care. The AMA is committed to ensuring that AI can meet its full potential to advance clinical care and improve clinician well-being. This may only be accomplished by ensuring that physicians engage only with AI that satisfies rigorous standards to meet the goals of the quadruple aim,[1] advance health equity, prioritize patient safety, and limit risks to both physicians and patients.

These new principles build on earlier AMA policy development activities, including the 2018 foundational AMA AI policy, Augmented Intelligence in Medicine,[2] followed by 2019 policy for payment and coverage of AI.[3] However, as AI has rapidly developed beyond AI-enabled medical devices, new policy and guidance for adoption of both device and non-device uses of AI-enabled technologies is necessary to assist in deployment of these new advances to physicians and patients. These principles will serve as the foundation for AMA's evolving advocacy on AI.

The AMA is dedicated to providing continued guidance to physicians on how to best engage with new AI-enabled technologies with the understanding that policy development related to AI will likely continue to develop given the rapid pace of change in this space.

Oversight of Health Care Augmented Intelligence

There is currently no national policy or governance structure in place to guide the development and adoption of non-device AI. While the Food and Drug Administration (FDA) regulates AI-enabled medical devices, many types of AI-enabled technologies fall outside the scope of FDA oversight, including AI that may have clinical applications, such as some clinical decision support functions. While the Federal Trade Commission and the Health and Human Services Office for Civil Rights have oversight over some aspects of AI, their authorities are limited and not adequate to ensure appropriate development and deployment of AI generally, and specifically in the health care space. The AMA encourages a whole of government approach to implement governance policies that ensure overall and disparate risks to consumers and patients arising from AI are mitigated to the greatest extent possible.

1. AI systems should enhance the patient experience of care and outcomes, improve population health, reduce overall costs for the health care system while increasing value, and support the professional satisfaction of physicians and the health care team.
2. American Medical Association. (2018). "AI in Healthcare: A Report from the American Medical Association Board of Trustees." AMA. https://www.ama-assn.org/system/files/2019-08/ai-2018-board-report.pdf (Accessed September 14, 2023).
3. American Medical Association. 2019). "AI in Healthcare: A Report from the American Medical Association Board of Trustees - 2019" https://www.ama-assn.org/system/files/2019-08/ai-2019-board-report.pdf (Accessed September 14, 2023).

- AMA next steps on AI policy and advocacy
- Addresses changing landscape of AI
- Provides more specific recommendations on certain policy/advocacy topics
- Focus on key areas ripe for additional action
  - National governance strategy and policy for AI
  - Transparency
  - Generative AI
  - Liability
  - Privacy and Security
  - Payor Use of AI
- 2023 AI Principles

AMA AI Advocacy

- **Goal:** ***Ensuring the design, development and deployment of healthcare AI is transparent, ethical, equitable, and responsible***.
- Regulatory Advocacy
  - Consensus standards and governance policies – thus far only voluntary standards/agreements
  - FDA: transparency requirements and updated labeling
  - ONC: Ensuring compliance with transparency requirement, potentially expanded transparency requirements
  - OCR: Limited physician liability for bad AI
  - FTC: Enforcement on false/deceptive AI, disclosure of use of AI, potential transparency requirements (?)
- Executive Order on AI: Number of healthcare/general directives

AMA Advocacy Priorities

- Legislative Advocacy
  - Building presence on Hill – primarily in education phase
    - Focus on transparency requirements, data privacy, payor use of AI
  - Participating in Member/Staff roundtable briefings
    - House AI Task Force: Reps. Obernolte/Lieu
    - Senate AI Working Group: Sens. Schumer/Heinrich/Rounds/Young
  - Unlikely to see congressional action soon – Rs leaning towards little regulation and deference to tech; Ds want to see additional regulation without stifling innovation

Hogan Lovells

AI: Understanding the Regulatory Environment and Payment

Cybil Roehrenbeck

Partner, Hogan Lovells LLP

AI Reimbursement

CMS AI Reimbursement

Physician Fee Schedule (PFS)

- AI reimbursed as part of the practice expense methodology of the PFS payment formula

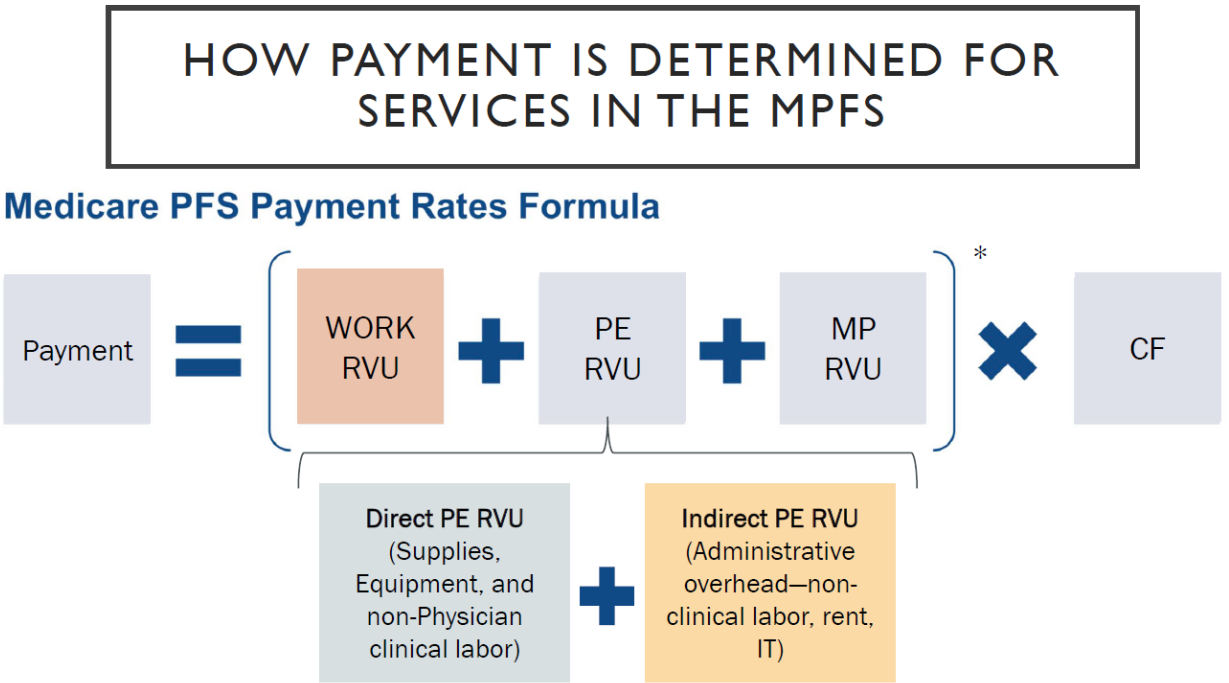
Outpatient Prospective Payment System (OPPS)

- AI reimbursed under a New Technology Ambulatory Payment Classification (New Tech APC) or a clinical APC
- New Tech APC-specific application (quarterly)

Inpatient Prospective Payment System (IPPS)

- AI reimbursed under a New Technology Add-on Payment (NTAP)
- NTAP-specific application

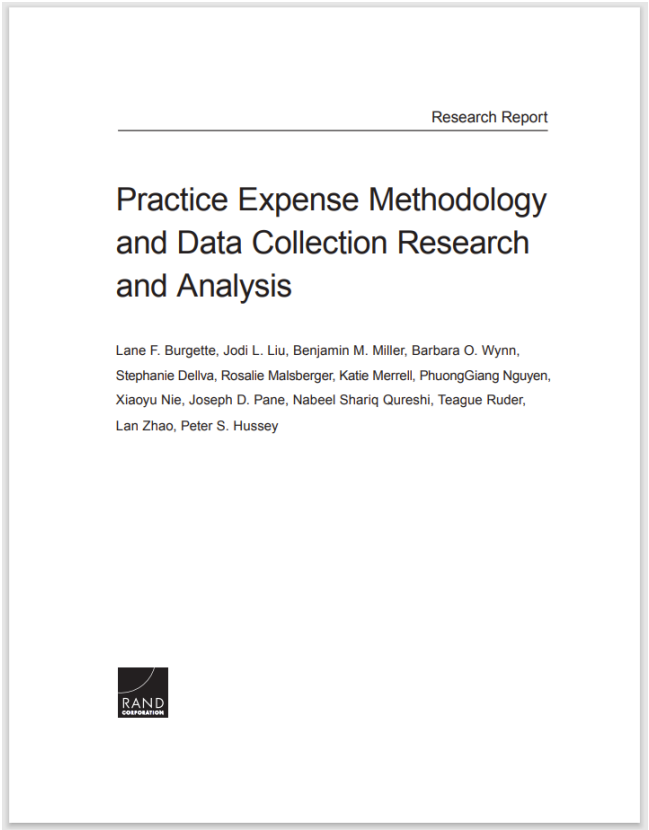
Medicare Physician Fee Schedule Reimbursement



* Each component is adjusted for geographic variation

Graphic adapted from Medicare Learning Network Booklet, MLN901344, March 2021

Medicare Physician Fee Schedule Reimbursement



Research Report

Practice Expense Methodology and Data Collection Research and Analysis

Lane F. Burgette, Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, PhuongGiang Nguyen, Xiaoyu Nie, Joseph D. Pane, Nabeel Shariq Qureshi, Teague Ruder, Lan Zhao, Peter S. Hussey

RAND CORPORATION

EXAMPLE: "PER CLICK" FEES

- Artificial Intelligence (AI) tools are starting to be used in clinical settings, e.g., to interpret images from eye exams
- When practices pay for these tools on a per-use basis, there are questions as to whether the payment should be paid as a direct or indirect expense
  - AI tools are not accounted for in current data
  - Practices may incur an expense that is directly tied to a specific patient encounter
  - Little additional indirect PE may be incurred for such services
- Transitioning away from rigid indirect/direct pools could provide flexibility for new expense types such as AI tools

Outpatient Prospective Payment System Reimbursement

- Certain services may qualify for payment as a New Technology Ambulatory Payment Classification (APC) under the Outpatient Prospective Payment System (OPPS).
- To be eligible, the service:
  - Could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.
  - Does not qualify for an additional payment under the transitional pass-through provisions
  - Cannot reasonably be placed in an existing clinical APC group
  - Falls within the scope of Medicare benefits
  - Reasonable and necessary
- New Technology APCs may be assigned for 2-3 years (or longer)
- Applications occur quarterly (first business day of March, June, September, December)

Inpatient Prospective Payment System Reimbursement

- Certain new medical services and technologies may be eligible for a New Technology Add-on Payment (NTAP) under the Inpatient Prospective Payment System (IPPS) per 42 CFR § 412.87(b).
- To qualify for an NTAP payment, three criteria must be met:
  - the medical service or technology must be **new**;
  - the medical service or technology must be **costly** such that the MS-DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; *and*
  - medical service or technology must demonstrate a **substantial clinical improvement** over existing services or technologies.
- Payments are limited to the lesser of 65% of the costs of the technology, or 65% of the amount by which the costs of the case exceed the standard MS–DRG payment
- Certain new medical services and technologies may be eligible to apply for NTAP under an alternative pathway. For example, technologies that are part of FDA's Breakthrough Devices Program may qualify.

CPT Coding –Total Claims

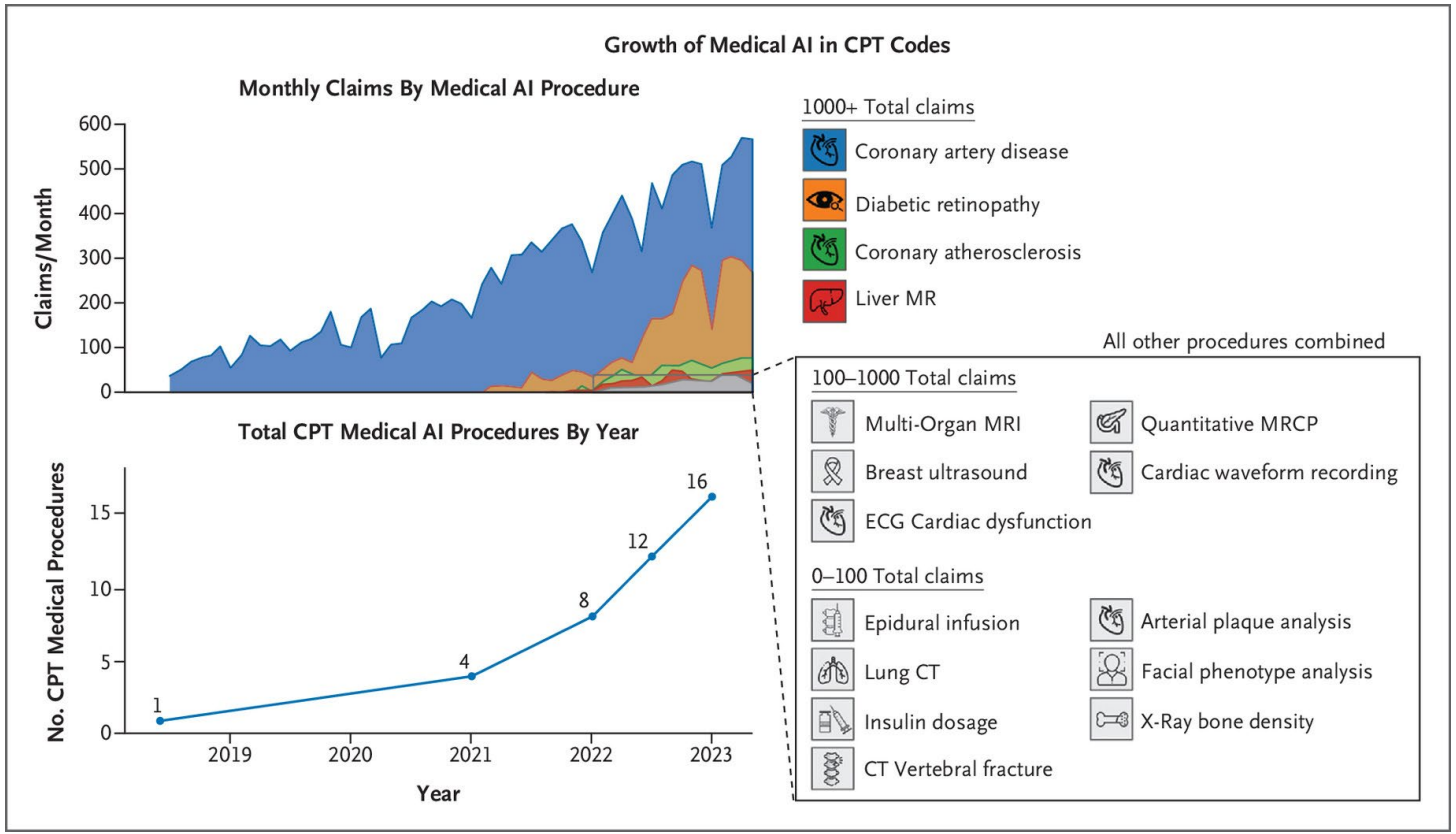
Table 1. Summary of AI CPT Codes.*

Total Claims	Condition or Medical AI Procedure	CPT Code(s)	Example Product Name	Effective Date
67,306	Coronary artery disease	0501T–0504T	HeartFlow Analysis[48]	June 1, 2018
15,097	Diabetic retinopathy	92229	LumineticsCore[49]	January 1, 2021
4,459	Coronary atherosclerosis	0623T–0626T	Cleerly[50]	January 1, 2021
2,428	Liver MR	0648T–0649T	Perspectum LiverMultiScan[51]	January 1, 2021
591	Multiorgan MRI	0697T–0698T	Perspectum CoverScan[52]	January 1, 2022
552	Breast ultrasound	0689T–0690T	Koios DS[53]	January 1, 2022
435	ECG cardiac dysfunction	0764T–0765T	Anumana[50]	January 1, 2023
331	Cardiac acoustic waveform recording	0716T	CADScor[50]	July 1, 2022
237	Quantitative MR cholangiopancreatography	0723T–0724T	Perspectum MRCP+[54]	July 1, 2022
67	Epidural infusion	0777T	CompuFlo[55]	January 1, 2023
4	Quantitative CT tissue characterization	0721T–0722T	Optellum Virtual Nodule Clinic[56]	July 1, 2022
1	Autonomous insulin dosage	0740T–0741T	d-Nav[57]	January 1, 2023
1	CT vertebral fracture assessment	0691T	HealthVCF[50]	January 1, 2022
1	Noninvasive arterial plaque analysis	0710T–0713T	ElucidVivo[50]	January 1, 2022
0	Facial phenotype analysis	0731T	Face2Gene[50]	July 1, 2022
0	X-ray bone density	0749T	OsteoApp[50]	January 1, 2023

* A total of 16 medical AI procedures are presented alongside their corresponding CPT codes. Each procedure is associated with an example commercial product that may be reimbursed through the codes. The effective date is the date on which the code was officially recognized by the American Medical Association and can be used for billing and reimbursement purposes. The total claims listed are recent as of June 1, 2023. AI denotes artificial intelligence; CPT, Current Procedural Terminology; CT, computed tomography; ECG, electrocardiogram; MR, magnetic resonance; MRCP, magnetic resonance cholangiopancreatography; and MRI, magnetic resonance imaging.

Wu et. al., "Characterizing the Clinical Adoption of Medical AI Devices through U.S. Insurance Claims" (November 9, 2023) NEJM AI 2023;1(1) DOI: 10.1056/AIoa2300030

CPT Coding – Total Claims



Wu et. al., "Characterizing the Clinical Adoption of Medical AI Devices through U.S. Insurance Claims" (November 9, 2023) NEJM AI 2023;1(1) DOI: 10.1056/AIoa2300030

Coverage - TCET Pathway

- On June 22, 2023, the Centers for Medicare & Medicaid Services (CMS) released a Notice with Comment Period (Notice) proposing a new Transitional Coverage for Emerging Technologies (TCET) pathway.
- The long-anticipated TCET pathway creates a new mechanism to provide Medicare patients with more timely and predictable access to medical devices with Breakthrough Device designation from the Food and Drug Administration (FDA).
- TCET features **early and voluntary manufacturer engagement with CMS**, **national coverage for three to five years pending development of evidence** to support more permanent national or local coverage, and opportunities for public comment.
- Due to CMS resource constraints, the agency anticipates **a small number of medical devices (approximately five per year) being accepted for TCET**.
- Significantly, CMS notes that devices that are not paid separately, such as devices furnished under the inpatient payment system, are coverable without TCET.

See A Break for Breakthrough Devices? CMS Issues Transitional Coverage for Emerging Technologies Notice | Hogan Lovells - JDSupra

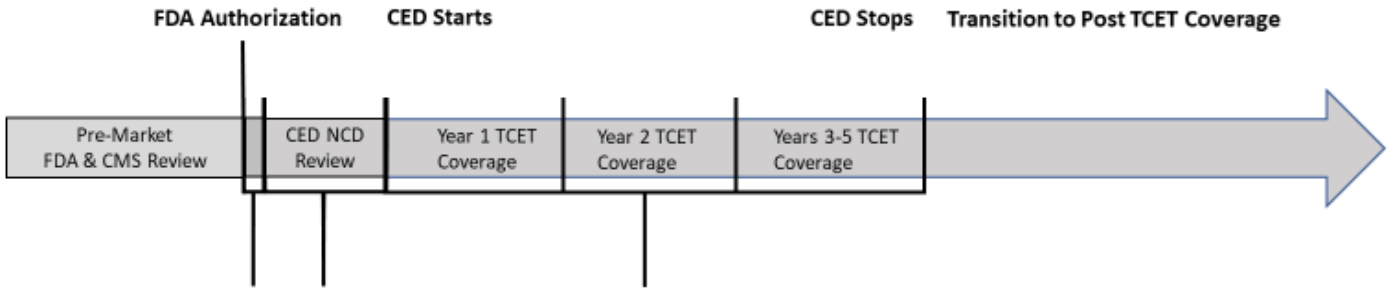
Coverage - TCET Pathway

- Two primary advantages to the TCET pathway.
  - The first is early feedback from CMS on clinical evidence and a plan for developing clinical evidence.
  - The second is national coverage for 3-5 years while that evidence is gathered.
- Evidence development
  - Greater certainty & collaborative process
  - Evidence Development Plan
- Transitional Coverage
  - 3-5 years of temporary national coverage following FDA marketing authorization while the EDP is executed and evidence is developed.
  - Coverage would be established via the NCD process following the statutory timeframes in section 1862(l) of the Social Security Act, including the 30-day comment period on proposed NCDs.
  - The NCD would need to be requested by the manufacturer, proposed by CMS, open to comment from the public, and eventually finalized.

See A Break for Breakthrough Devices? CMS Issues Transitional Coverage for Emerging Technologies Notice | Hogan Lovells - JDSupra

Coverage - TCET Pathway

TCET Proposed Pathway/ Timeline



Legend: TCET = Transitional Coverage for Emerging Technologies; FDA = Food and Drug Administration; CED = Coverage with Evidence Development; CMS = Centers for Medicare and Medicaid Services; NCD = National Coverage Determination; EDP = Evidence Development Plan; NCA = National Coverage Analysis; MAC = Medicare Administrative Contractor.

Understanding the AI Taxonomy

CPT Codes and the Pathway to Payment

Samantha Ashley, MS – Director, CPT Editorial and Regulatory Affairs

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Reimbursement-related information provided by the AMA and contained in this presentation is for medical coding guidance purposes only. It does not (i) supersede or replace the AMA's Current Procedural Terminology (CPT®) manual ("CPT Manual") or other coding authority, (ii) constitute clinical advice, (iii) address or dictate payer coverage or reimbursement policy, or (iv) substitute for the professional judgement of the practitioner performing a procedure, who remains responsible for correct coding.

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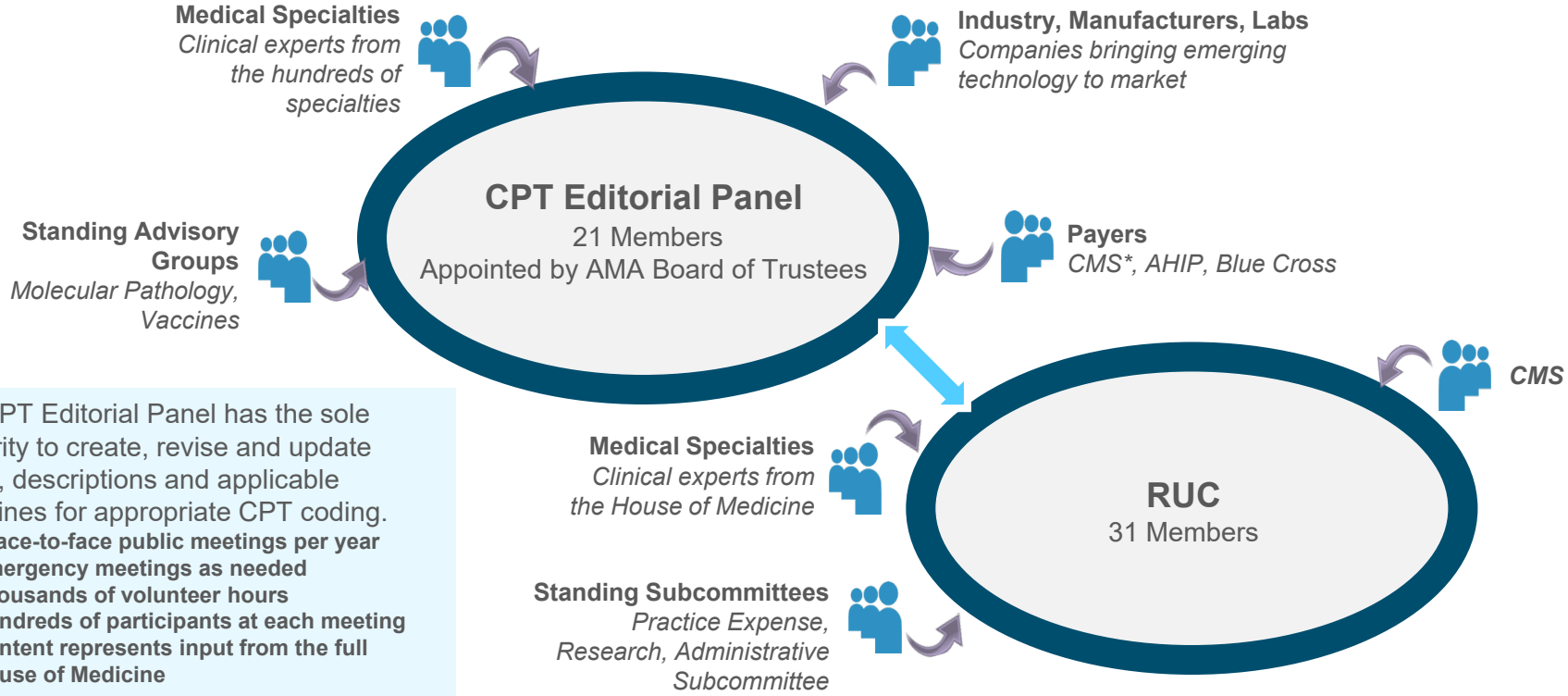
CPT® Appendix S: AI taxonomy for medical services & procedures

A Framework for Describing AI Services

CPT® Editorial Panel relationship to the RUC

Evidence-based | **Deliberation driven** | **Well-defined criteria** | **Clinical expertise**



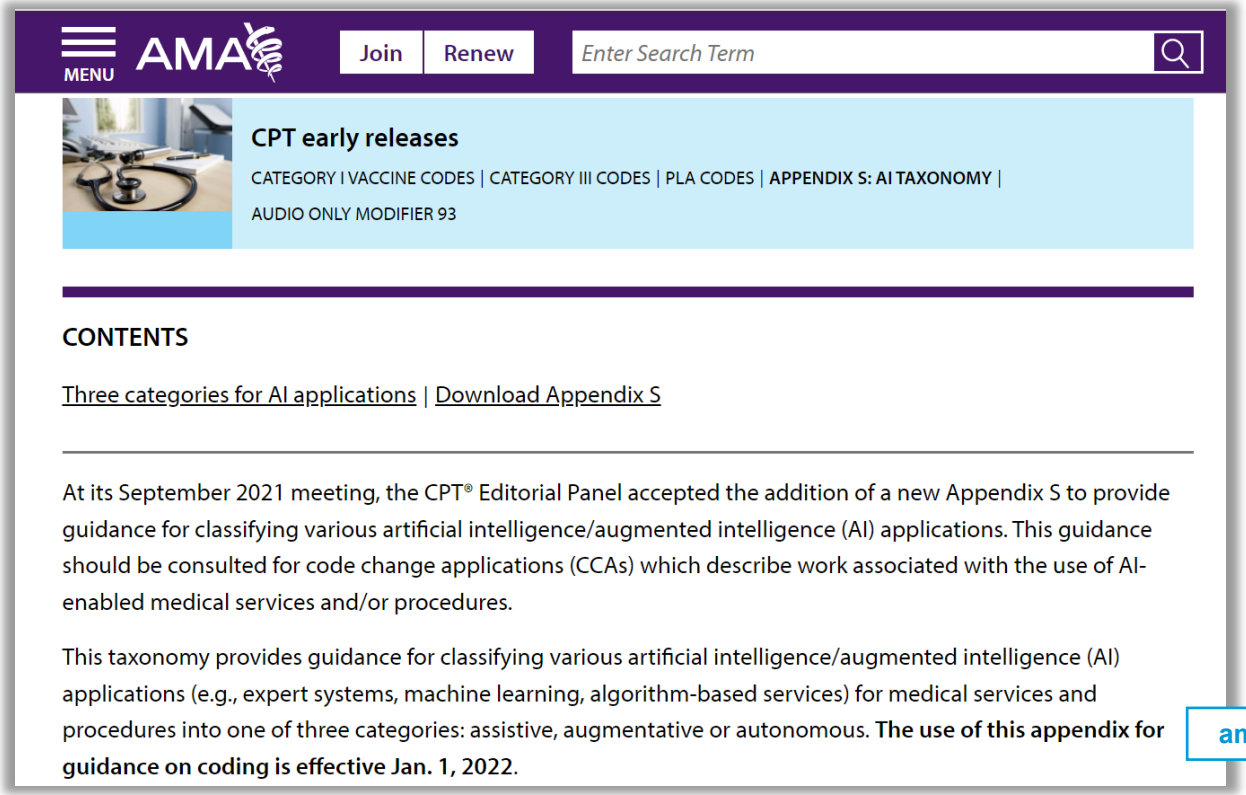
The CPT Editorial Panel has the sole authority to create, revise and update codes, descriptions and applicable guidelines for appropriate CPT coding.

- **3 face-to-face public meetings per year**
- **Emergency meetings as needed**
- **Thousands of volunteer hours**
- **Hundreds of participants at each meeting**
- **Content represents input from the full House of Medicine**

*CMS has observer status. Also, members do not advocate for their specialty or organization once named to the Panel.

CPT® Appendix S: AI taxonomy for medical services & procedures

New appendix:
AI taxonomy for medical services & procedures

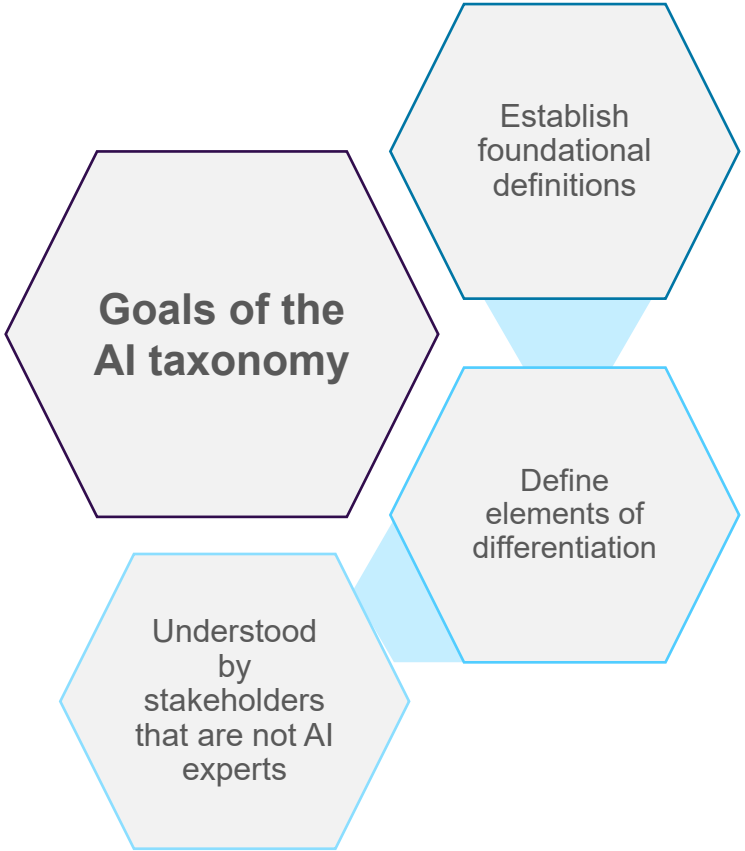


ama-assn.org/cpt-ai-taxonomy

CPT® Appendix S: AI taxonomy for medical services & procedures

The AI Taxonomy provides and defines distinct categories to describe the work done by the machine on behalf of the physician based on:

- Technical features and performance of emerging AI products and services
- Effect on the work of the physician/QHP
- Discrete components of work in order to facilitate valuation



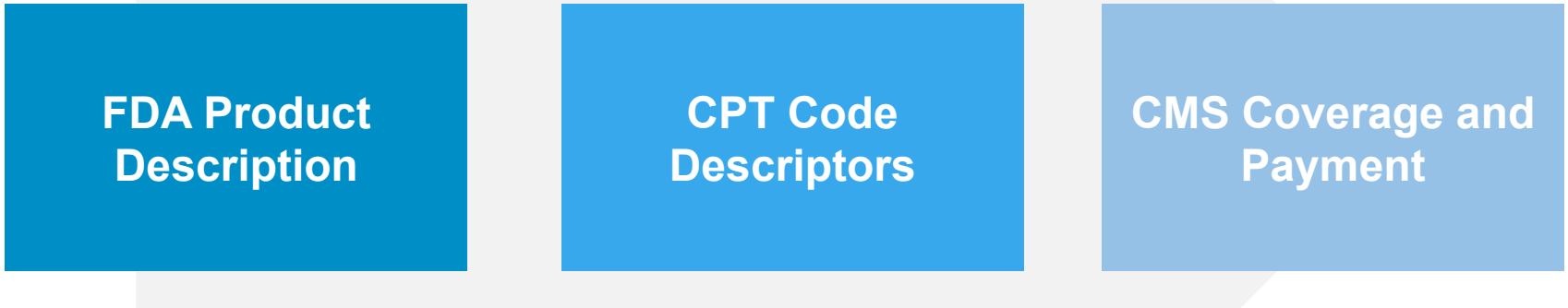
CPT® Appendix S: AI taxonomy for medical services & procedures

CPT®: Supporting innovation along the pathway to payment

The goals of the AI Taxonomy are very specific to **CPT coding**, the descriptive nomenclature for the work of the physician or other qualified health professional to provide a medical service.

CPT coding is distinct from payment but has important downstream impacts on valuation and payment.

CPT® code descriptors anchor the continuum



npj | digital medicine

www.nature.com/npjdigitalmed

PERSPECTIVE OPEN

Check for updates

Developing current procedural terminology codes that describe the work performed by machines

Richard A. Frank[1,2✉], Robert Jarrin[1,3], Jordan Pritzker[1,4], Michael D. Abramoff[1,5,6], Michael X. Repka[1,7], Pat D. Baird[1,8], S. Marlene Grenon[1,9], Megan Ruth Mahoney[1,10], John E. Mattison[1,11] and Ezequiel Silva III[1,12,13]

The "Taxonomy of Artificial Intelligence for Medical Services and Procedures" became part of the Current Procedural Terminology (CPT®) code set effective January 1, 2022. It provides a framework for discrete and differentiable CPT codes which; are consistent with the features of the devices' output, characterize interaction between the device and the physician or other qualified health care professional, and foster appropriate payment. Descriptors include "Assistive", "Augmentative", and "Autonomous". As software increasingly augments the provision of medical services the taxonomy will foster consistent language in coding enabling patient, provider, and payer access to the benefits of innovation.

npj Digital Medicine (2022)5:177 ; https://doi.org/10.1038/s41746-022-00723-5

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The link has additional benefits over uploading or emailing a static PDF; readers using the shared link will be able to use Enhanced PDF features such as annotation tools, one-click supplements, citation file exports and article metrics.

CPT® Appendix S: AI taxonomy for medical services & procedures

Content

AI Taxonomy: Introductory language

> This taxonomy provides guidance for classifying various artificial intelligence (AI) applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of these three categories: assistive, augmentative, and autonomous. AI as applied to health care may differ from AI in other public and private sectors (e.g., banking, energy, transportation). **Note that there is no single product, procedure, or service for which the term "AI" is sufficient or necessary to describe its intended clinical use or utility; therefore, the term "AI" is not defined in the code set.** In addition, the term "AI" is not intended to encompass or constrain the full scope of innovations that are characterized as "work done by machines." Classification of AI medical services and procedures as assistive, augmentative, and autonomous is based on the clinical procedure or service provided to the patient and the work performed by the machine on behalf of the physician or other qualified health care professional (QHP)."

AI Taxonomy:
Categorization & level of autonomy

Assistive:

The work performed by the machine for the physician or other qualified health care professional is assistive when the machine **detects** clinically relevant data without analysis or generated conclusions. Requires physician or other qualified health care professional interpretation and report.

Augmentative:

The work performed by the machine for the physician or other qualified health care professional is augmentative when the machine **analyzes and/or quantifies** data to yield clinically meaningful output. Requires physician or other qualified health care professional interpretation and report.

AI Taxonomy: Categorization & level of autonomy

Autonomous:

The work performed by the machine for the physician or other qualified health care professional is autonomous when the machine automatically **interprets data and independently generates clinically meaningful conclusions** without concurrent physician or other qualified health care professional involvement. An autonomous medical service includes interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically meaningful conclusion may be a characterization of data (e.g., likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. There are three levels of autonomous AI medical services and procedures with varying physician or other qualified health care professional involvement:

I.

The autonomous AI draws conclusions and offers diagnosis and/or management options, is contestable and requires physician or other qualified health care professional action to implement.

II.

The autonomous AI draws conclusions and initiates diagnosis and/or management options with alert/opportunity for override, may require physician or other qualified health care professional action to implement.

III.

The autonomous AI draws conclusions and initiates management, requires physician or other qualified health care professional action to contest.

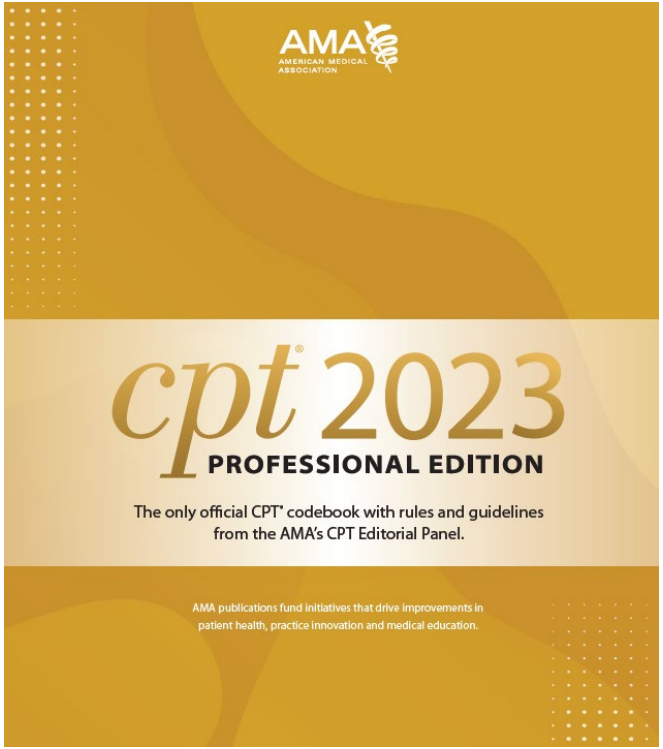
AI Taxonomy: Table

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data to yield clinically meaningful output	Interprets data and independently generates clinically meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other qualified health care professional interpretation and report	Yes	Yes	No
Examples in CPT code set	Algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (0764T, 0765T)	Noninvasive estimate of coronary fractional flow reserve (FFR) (75580)	Retinal Imaging (92229)

AI taxonomy implementation

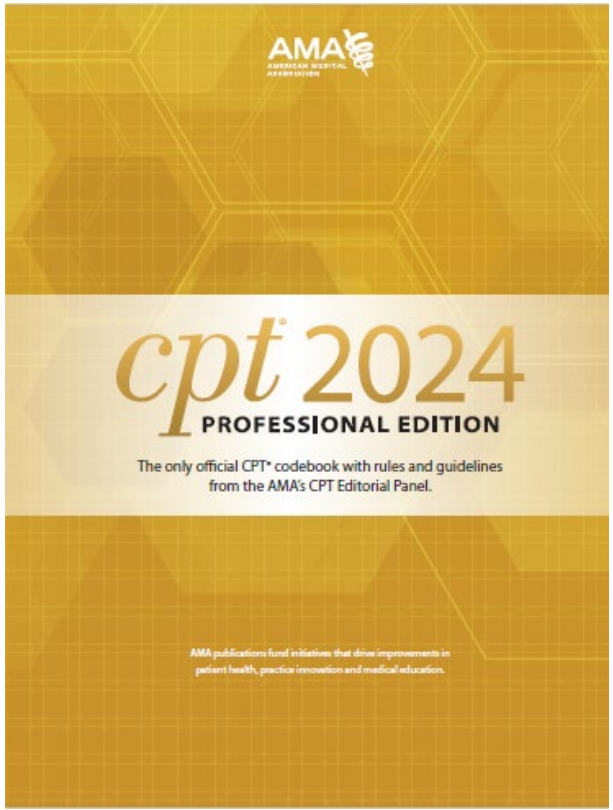
Precedent for Autonomous

- CPT® Code 92229 is the only Category I code that currently fits into the category of autonomous.
- Previous code descriptor:
  - **92229** *Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral*
- At the February 2022 meeting the Panel accepted revision of code 92229 by removing the term “automated” and replacing it with “autonomous”.
- Revised code descriptor:
  - **92229** *Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*



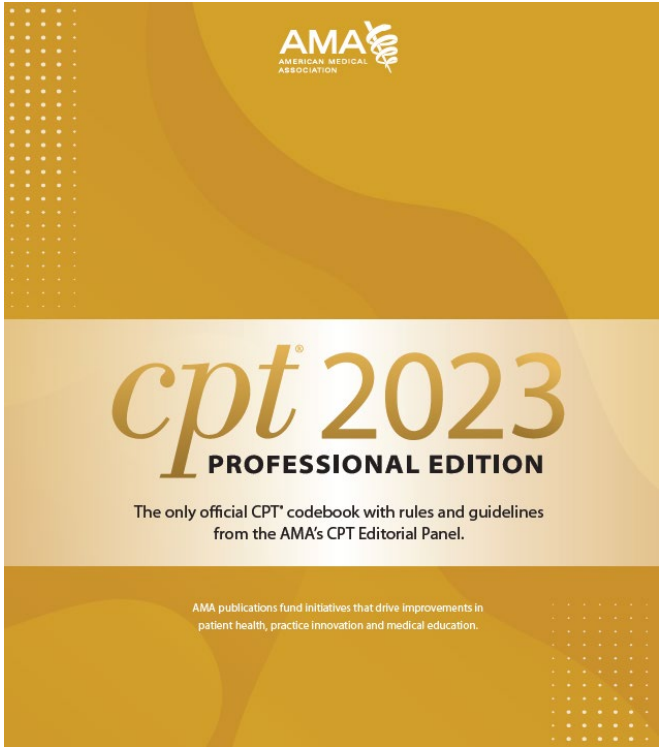
Precedent for Augmentative

- CPT® Code 75580 is the only Category I code that currently fits into the category of augmentative.
- At the September 2022 meeting the Panel accepted CPT code 75580.
- Revised code descriptor:
    - **75580** *Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*



Precedent for Assistive

- CPT® codes 0764T and 0765T are category III codes that fit into the category of assistive.
  - **0764T** *Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)*
  - **0765T** *Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram*



CPT® resources: For more information

Visit the **CPT code set quick reference guide** to learn more about AMA and CPT resources on:

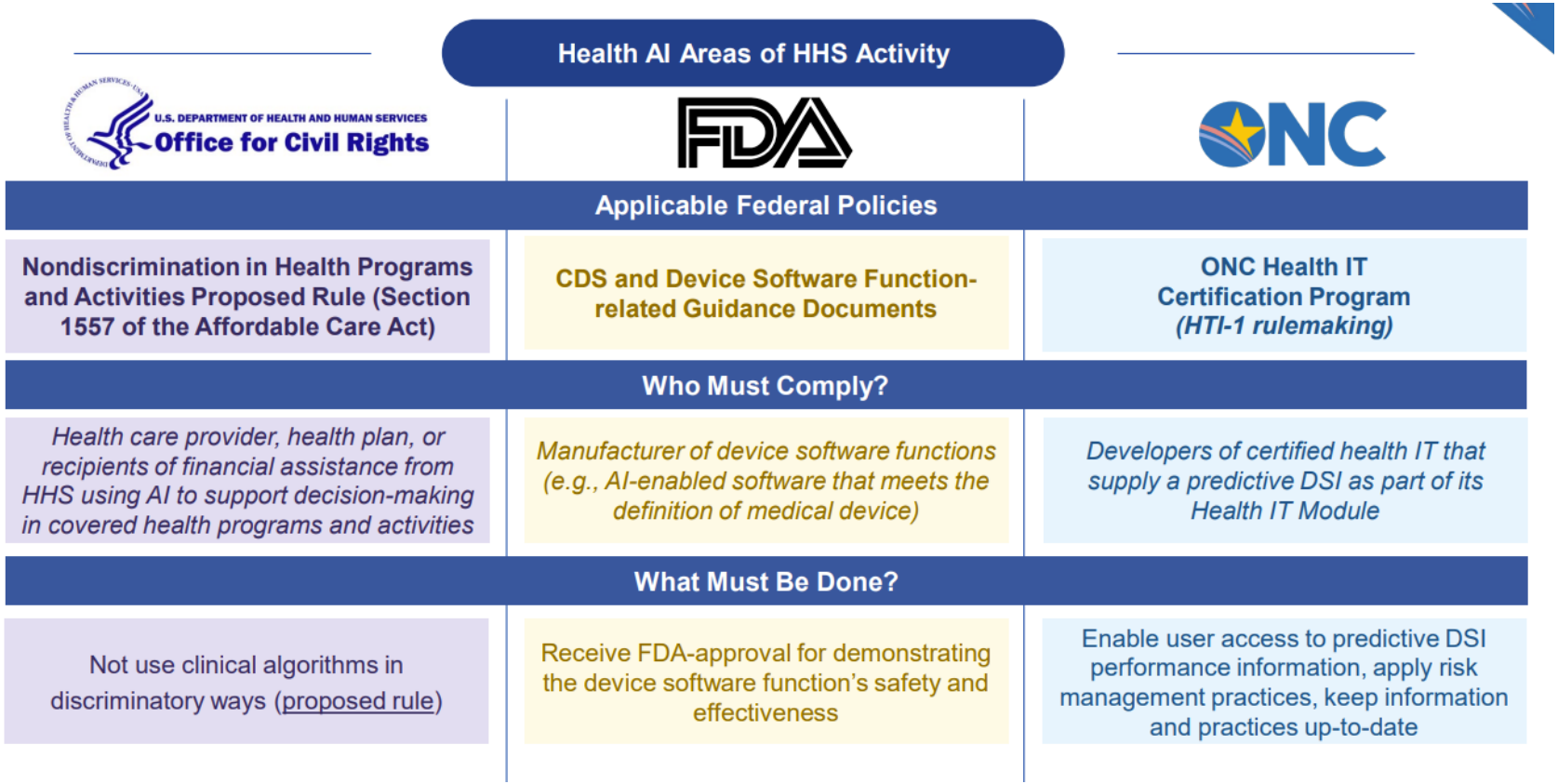
- ✓ The CPT Editorial Panel Process, including code change application details and the CPT Editorial Panel meetings calendar
- ✓ CPT News, for the latest in CPT codes and content
- ✓ Innovation and Technology
- ✓ Medical Practice Management
- ✓ Health Equity
- ✓ And… sending in your questions!

ama-assn.org/cpt-resources-guide

Physicians' powerful ally in patient care

Recently-released Health AI Rules

Across HHS Efforts



New AI Rules for Certified HIT

What is the new ONC AI rule for certified HIT?

- The HHS Office of the National Coordinator (ONC) recently released its final rule on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*.
- The HTI-1 final rule updated functionality, configuration, and transparency requirements for the decision support intervention (DSI) criterion and clarified that health IT developers are responsible for only the Predictive DSIs that they supply as part of their certified health IT.
- Among other requirements, health IT developers will need to comply with certain ongoing maintenance requirements to keep their DSI "source attribute" information complete and up to date as well as implement risk management practices for Predictive DSIs they supply to address risk analysis, risk mitigation, and governance.

New AI Rules for Certified HIT

What is the scope of the ONC HIT rule? Do I have to report?

- ONC changed "enabled or interfaced with" in the proposed rule to "supplied by" in the final rule to reflect its intent to "only apply additional Predictive DSI related stewardship responsibilities to health IT developers who supply Predictive DSIs as part of their Health IT Module" and narrow the focus of these requirements, reducing the overall scope of technologies subject to these specific requirements.
- According to the HTI-1 Preamble, ONC interprets "supplied by" to include "interventions authored or developed by the health IT developer as well as interventions authored or developed by another party that the health IT developer includes as part of its Health IT Module, such as stated in the comments, 'when entities have contracts specifically covering the enablement and use of such technologies.'"
- (Note: another party means any party that develops a DSI, a model, or an algorithm that is used by a DSI and is not the developer of certified health IT or a subsidiary of the developer of certified health IT.)

New AI Rules for Certified HIT

I have an FDA-authorized AI system – is it exempt from ONC's new DSI rule?

- No. ONC declined to exclude FDA-regulated SaMD from the definition of "predictive DSI"—and associated disclosure and reporting requirements for Certified HIT developers.
- Specifically, ONC noted in the final rule preamble:
  - *Comment. Several commenters expressed concern about consistency, duplication, and redundant requirements across various federal programs. Commenters recommended that ONC tailor the scope of the proposed term Predictive DSI, and the proposed definition at § 170.102, to exclude FDA-authorized AI and machine learning medical devices to mitigate their concerns mentioned above….*
  - *Response. …We appreciate the suggestions to exclude from our definition for Predictive DSI software that are regulated medical devices and to exclude third-party software that qualify as non-device software functions per the statutory exemption for CDS software. However, we decline to include any exclusionary criteria in our definition for Predictive DSI…*

New AI Rules for Certified HIT

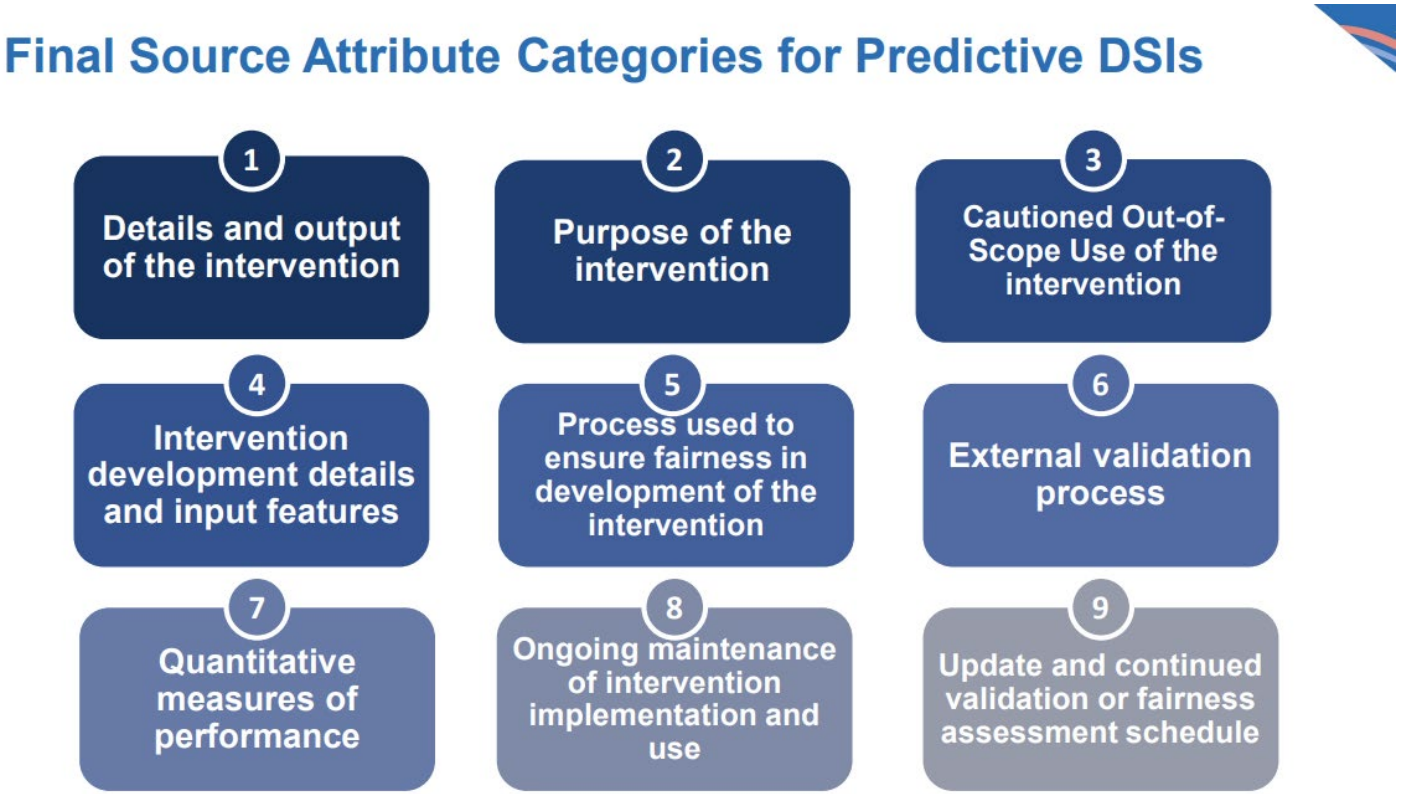
Evidence-based DSI Source Attributes

Health IT Modules are required to enable a user to review “source attributes” information

Bibliographic citation of the intervention
Developer of the intervention
Funding source of the intervention
Release, and if applicable, revision date(s) of the intervention

NEW: Use of race, ethnicity, language, sexual orientation, gender identity, sex, age
NEW: Use of social determinants of health data
NEW: Use of health status assessment data

New AI Rules for Certified HIT



New AI Rules for Certified HIT

Activities to consider as part of IRM Practices

Should include:

- Estimates of the likelihood and magnitude of the negative impact (harm), or consequences, of each risk characteristic
- To whom each risk applies (including, for example, individual, group, and societal harm)
- Source of each risk

Should include:

- Practices used to prioritize or establish different levels of risk
- Practices to mitigate or minimize identified risks
- Change control plans or ongoing validation and updating processes
- Processes to supersede, disengage, or deactivate deviations from intended use
- Approaches to include SMEs in measuring/validating performance

Should include:

- Setting an effective framework for risk management, with defined roles and responsibilities for clear communication of predictive DSI limitations and assumptions
- Setting and enforcing priorities for managing and using data as a strategic asset

Sec. 1557 Non-Discrimination Rule

- In 2022, OCR and CMS issued a Notice of Proposed Rulemaking (NPRM) to reinterpret Section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in, among other things, a health program or activity for which any part receives federal financial assistance.
- The Final Rule, which was recently released, applies the nondiscrimination principles under Section 1557 to use of newly defined "patient care decision support tools" in clinical care and requires those subject to the rule to identify and mitigate discrimination when they use patient decision support tools, including automated and non-automated tools, mechanisms, methods, and technology to provide patient care.
- Covered entities are required to begin compliance with the new patient care decision support tool requirements within 300 days of the Final Rule's effective date.
- Under the Final Rule, covered providers also have an ongoing responsibility to identify their patient care decision support tools that directly measure race, color, national origin, sex, age, or disability, and to make reasonable efforts to mitigate the risk of discrimination from their use of these tools.
- The Final Rule's preamble also clarifies that Predictive DSIs as defined by ONC are a subset of "patient care decision support tools."
- While ONC's requirements for predictive DSIs apply to health information technology *developers*, Section 1557's requirements apply to covered entity *users* of patient care decision support tools, including Predictive DSIs.

OMB AI Final Guidance, Fact Sheet & RFI

- The White House Office of Management & Budget (OMB) has released its final guidance on AI procurement following President Biden's Executive Order on AI, as well as a fact sheet and request for information (RFI) regarding implementation of the guidance.
- The OMB guidance requires that agencies adopt certain safeguards for "rights impacting" or "safety impacting" AI, for example (per the fact sheet):
  - *"When AI is used in the Federal healthcare system to support critical diagnostics decisions, a human being is overseeing the process to verify the tools' results and avoids disparities in healthcare access."*
- **Safety impacting** AI includes:
  - Carrying out the medically relevant functions of medical devices; providing medical diagnoses; determining medical treatments; providing medical or insurance health-risk assessments; providing drug-addiction risk assessments or determining access to medication; conducting risk assessments for suicide or other violence; detecting or preventing mental-health issues; flagging patients for interventions; allocating care in the context of public insurance; or controlling health-insurance costs and underwriting;
- **Rights impacting** AI includes:
  - Carrying out the medically relevant functions of medical devices; providing medical diagnoses; determining medical treatments; providing medical or insurance health-risk assessments; providing drug-addiction risk assessments or determining access to medication; conducting risk assessments for suicide or other violence; detecting or preventing mental-health issues; flagging patients for interventions; allocating care in the context of public insurance; or controlling health-insurance costs and underwriting

More Agency Activity - FDA AI White Paper

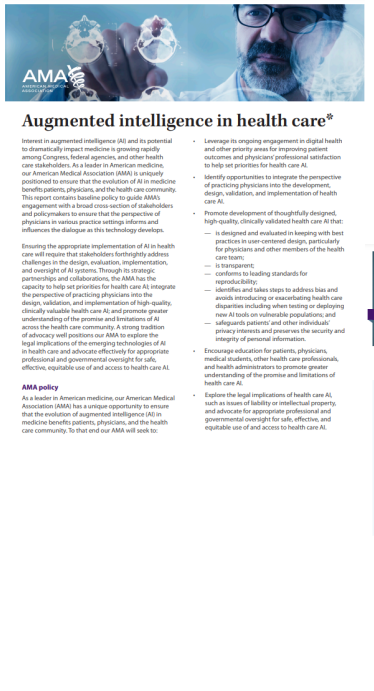
- FDA released a white paper on its work around AI.
- While few details were included, the paper did stated that they intend to solicit input from stakeholders in a number of areas, including transparency, explainability, governance, bias, cybersecurity, and quality assurance.
- They also noted that they intend to issue final and draft guidance in a number of areas.

Hogan Lovells

www.hoganlovells.com

AMA Resources - Policies, Principles, & Perspectives

- Augmented Intelligence in Healthcare (2018)
  - AMA Board Report on current landscape, opportunity, and physician role
- Payment and Regulation of AI (2019)
  - First effort at AMA AI policy
  - Set tone for broad principles around regulation of AI and for reimbursement of AI



Summary of Physician Sentiments on AI

There is enthusiasm around augmented intelligence and its role in health care.

- 65% of physicians see an advantage to AI.
- The greatest enthusiasm is around AI tools that can help reduce administrative burdens including documentation (54%) and prior authorization (48%).

There is both excitement and concern about the potential for AI in healthcare.

- 41% of physicians responded that they were both equally excited and concerned.
- Physicians indicated that they see the most promise for AI to support diagnosis (72%) and workflow (69%).
- Physicians are most concerned about the impact to the patient-physician relationship (39%) and patient privacy (41%).

The most common AI tools physicians are using in practice today or plan to soon focus on addressing administrative burden.

- Only 38% of physicians are currently using AI in practice, with the most common uses being for various forms of documentation, translation services, and assisting with diagnosis.
- 56% of physicians indicated that AI can best help with administrative burdens through automation.
- Generation of patient messages and chart summaries, and prediction of demand and associated workforce needs are top areas where physicians plan to implement AI within the next 5 years.

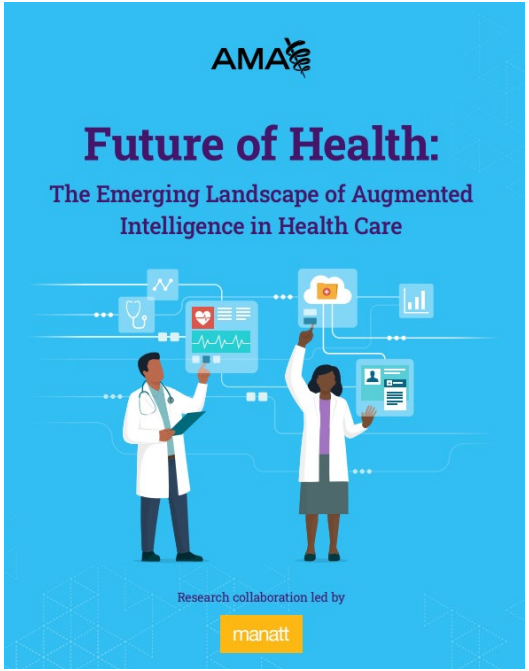
Resources and support will be crucial for physician adoption of AI.

- Data privacy assurances, being not liable for AI model errors, and malpractice insurance coverage are most important for advancing adoption.
- 35% of physician respondents indicated that clinical evidence was the most helpful resource.

Physician Sentiment Survey

AMA Future of Health: Emerging Landscape of Augmented Intelligence in Health Care

- New AMA physician-focused resource on AI
- Overview of the current landscape for AI
- Efforts at common AI vocabulary
- Describes current and potential future AI use cases
- Highlights opportunities and risks
- Lays out considerations for use of AI in your practice
- AMA Future of Health Report



Questions

Digital Quality Series

Moving to Digital Quality Measurement Series –

- This three-part webinar series will focus on the health care industry's movement to digital quality measurement. The first webinar, Making Measurement Efficient – Moving to Digital Quality Measurement, will feature speakers from the National Committee for Quality Assurance (NCQA), NAACOS, EPIC and MultiCare Connected care to unpack the benefits and challenges of moving to a more digital quality measurement and reporting approach. The second in the series will discuss policy implications for digital quality measurement and will feature government speakers who will share their vision for the digital quality future. The final webinar in the series will provide listeners with tactics to prepare for the retirement of the Web Interface quality reporting tool and will feature three ACOs who have embarked on new reporting pathway efforts.

Digital Quality Webinar Series: Making Measurement Efficient- Moving to Digital Quality Measurement

July 8th, 3-4PM Eastern Time

This webinar will focus on the movement to digital quality measurement by the health care industry, including the use of bulk Fast Healthcare Interoperability Resources (FHIR) for more efficient quality reporting. Speakers will discuss current digital quality measurement approaches and the benefits and challenges of moving to a more digital measurement approach. **Register here**.

Upcoming Events

- NAACOS Fall Conference:

  October 16-18, 2024

  Marriott Marquis Washington, D.C.

  Registration now open!

Upcoming Events

Virtual Affinity Group Meetings - Register here

- **Operations Affinity Group**

Meets: October 29, 2024, from 3–4 pm ET.
Participants should include managers and others who oversee day-to-day aspects of running an ACO such as building provider networks, engaging patients, practice transformation, and implementing projects to achieve the ACO's financial and strategic goals, etc.

- **Quality Affinity Group**

Meets: November 5, 2024, from 3–4 pm ET.
Participants should include managers and others who implement initiatives designed to improve, measure, and report the quality of care in an ACO, etc.

- **Data and Analytics Affinity Group**

Meets: July 9 and November 12, 2024, from 3–4 pm ET.
Participants should include managers within ACOs who are responsible for integration, using data to analyze performance, creating and integrating data from sources like EMRs, claims and registries, etc.

Upcoming Events

Virtual Affinity Group Meetings

- **Executive Affinity Group**

Meets: July 16 and November 19, 2024, from 3–4 pm ET.
Participants should include CEOs, CFOs, Executive Directors, Chief Value Officers, and others who oversee the ACO's finances, budget, strategy, contracting, etc.

- **CMO and Clinical Affinity Group**

Meets: July 23 and December 3, 2024, from 3–4 pm ET.
Participants should include CMOs, CNOs, Pop Health Officers, and others who manage patient care, and clinical care redesign, etc.

- **Compliance and Legal Affinity Group**

Meets: July 30, and December 10, 2024, from 3–4 pm ET.
Participants should include those who ACO leaders and staff members who deal with compliance documentation, operations, or events as well as those who deal with ACO contracting with payers and participants.

Upcoming Events

- Practice Transformation Learning Lab Register Here - fourth Friday of each month from 12:00-1:30 pm ET)
- Topics include:
  - Where to start in practice transformation
  - Managing the care team: Taking action on practice redesign
  - Understanding available population health data
  - Combining data for population health initiatives
  - Developing or redesigning clinical care models
  - Population health tools: What works for your practice/ACO
  - Payor/Provider contracts and financial distribution models
  - Managing ED and hospital events
  - Developing a post-acute network
  - Advanced care models (home care, BH, SDOH support)